UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

RAMONA LONGS, as Executor of the Estate of Mary Buchanan,	)	Case No.: 1:03 CV 2042
Plaintiff	)	
v.	)	JUDGE SOLOMON OLIVER, JR.
WYETH, *et al.*,	)	
Defendants	)	ORDER

Plaintiff Ramona Longs[1] ("Plaintiff" or Longs") brings the above-captioned lawsuit as executor of the estate of decedent Mary Buchanan ("Buchanan"), alleging product liability claims against Defendants Wyeth, *et al.* (collectively, "Defendants" or "Wyeth").[2] Now pending before

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[1] The within case was originally brought by Mary Buchanan, who was terminated due to her death. The Amended Complaint named Ramona Longs, as well as two other persons, all in their individual capacities; however, all claims by individual plaintiffs were dismissed by agreement of both parties. (*See* ECF Nos. 32, 38, 11/28/07 Order [non-document].) Consequently, the sole remaining Plaintiff is Ramona Longs in her role as executor. Therefore, the court will refer to Plaintiff in the singular throughout this Order.

[2] The docket indicates that the remaining Defendants are Wyeth (formerly known as American Home Products Corporation), Wyeth-Ayerst Laboratories Company, Wyeth Pharmaceuticals, Inc., and Wyeth Pharmaceuticals. All entities are represented by the same counsel. Plaintiff's Amended Complaint alleges that Wyeth has assumed liability for each of the other Defendants, which are either wholly-owned subsidiaries of Wyeth (*i.e.*, Wyeth-Ayerst Laboratories Company and Wyeth Pharmaceuticals, Inc.) or divisions of Wyeth (*i.e.*, Wyeth Pharmaceuticals). (Am.

the court are Defendants' Motion for Partial Summary Judgment Based on Federal Preemption (ECF No. 34); Defendants' Motion for Summary Judgment Based on Lack of Evidence of Proximate Causation (ECF No. 31); and Defendants' Motion for Partial Summary Judgment Relating to Punitive Damages (ECF No. 33). For the reasons stated below, the Motions are denied as moot to the extent that they address Plaintiff's failure to warn claim, which Plaintiff has withdrawn. Consequently, Plaintiff's failure to warn claim is hereby dismissed with prejudice. Furthermore, Defendants' Motion for Partial Summary Judgment Based on Federal Preemption (ECF No. 34) is granted in part and denied in part; Defendants' Motion for Summary Judgment Based on Lack of Evidence of Proximate Causation (ECF No. 31) is granted, and Defendants' Motion for Partial Summary Judgment Relating to Punitive Damages (ECF No. 33) is denied as moot. As a result of the above rulings, Plaintiff's case is hereby dismissed in its entirety.

I. FACTS AND PROCEDURAL HISTORY

According to Plaintiff, Buchanan ingested the diet pill Redux for several months during 1996 and 1997. (Am. Compl. ¶ 6.) In November, 2001, Buchanan was diagnosed with primary pulmonary hypertension ("PPH"). (*Id.* ¶ 7.) Buchanan died on December 18, 2003, allegedly as a result of PPH. (*Id.*)

Defendants marketed and sold the drug Redux. (Answer 2-3, 8, ECF No. 4.) Redux was approved by the FDA in April, 1996. (*See* FDA Approval Letter, Defs.' Ex. A, ECF No. 33.) Redux became available to the public in June, 1996 (4/30/96 Letter, Defs.' Ex. E, ECF No. 31) and was taken off the market on or about September 15, 1997. (Answer ¶ 26.)

Plaintiff's Amended Complaint alleges the following claims: (1) product liability, which

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Compl. ¶ 5, ECF No. 18.)

encompasses both design defect, pursuant to O.R.C. § 2307.75, and failure to warn, pursuant to O.R.C. § 2307.76; (2) negligence; and (3) wrongful death, pursuant to O.R.C. § 2125.01 *et seq.* (Am. Compl. ¶¶ 14-22.) Plaintiff seeks economic and non-economic damages (*id.* at 9), as well as punitive damages, pursuant to O.R.C. § 2307.80(C). (*Id.* ¶ 13.) On October 3, 2007, Plaintiff filed a Notice of Withdrawal of Claim of Failure to Warn. (ECF No. 35.) In the Notice, Plaintiff stated that she intended to pursue only her design defect and negligence claims, and that she continued to seek punitive damages. (*Id.* at 1-2.)

The court held oral arguments on January 17, 2008, at which the parties addressed Defendants' Motion for Partial Summary Judgment Relating to Punitive Damages and Defendants' Motion for Summary Judgment Based on Lack of Evidence of Proximate Causation. At oral argument, both parties indicated that they rested on their briefs as to Defendants' Motion for Partial Summary Judgment Based on Federal Preemption. (1/17/08 Oral Argument Tr. ("1/17/08 Tr.") at 44) (on file.)

II. SUMMARY JUDGMENT STANDARD

Federal Rule of Civil Procedure 56(c) governs summary judgment motions and provides:

> The judgment sought shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law . . . .

In reviewing summary judgment motions, this court must view the evidence in a light most favorable to the non-moving party to determine whether a genuine issue of material fact exists. *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 153 (1970); *White v. Turfway Park Racing Ass'n, Inc.*, 909 F.2d 941, 943-44 (6th Cir. 1990). A fact is "material" only if its resolution will affect the

outcome of the lawsuit. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Determination of whether a factual issue is "genuine" requires consideration of the applicable evidentiary standards. Thus, in most civil cases the Court must decide "whether reasonable jurors could find by a preponderance of the evidence that the [non-moving party] is entitled to a verdict." *Id.* at 252. However, "[c]redibility judgments and weighing of the evidence are prohibited during the consideration of a motion for summary judgment." *Ahlers v. Scheibil*, 188 F.3d 365, 369 (6th Cir. 1999).

Summary judgment is appropriate whenever the non-moving party fails to make a showing sufficient to establish the existence of an element essential to that party's case and on which that party will bear the burden of proof at trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). Moreover, "the trial court no longer has a duty to search the entire record to establish that it is bereft of a genuine issue of material fact." *Street v. J.C. Bradford & Co.*, 886 F.2d 1472, 1479-80 (6th Cir. 1989) (citing *Frito-Lay, Inc. v. Willoughby*, 863 F.2d 1029, 1034 (D.C. Cir. 1988)). The non-moving party is under an affirmative duty to point out specific facts in the record as it has been established that create a genuine issue of material fact. *Fulson v. City of Columbus*, 801 F. Supp. 1, 4 (S.D. Ohio 1992). The non-movant must show "more than a scintilla of evidence to overcome summary judgment"; it is not enough to show that there is slight doubt as to material facts. *Id.*

> When a motion for summary judgment is made and supported as provided in this rule, an adverse party may not rest upon the mere allegations or denials of the adverse party's pleading, but the adverse party's response, by affidavits or as otherwise provided in this rule, must set forth specific facts showing that there is a genuine issue for trial.

Fed. R. Civ. P. 56(e).

III. MOTION FOR PARTIAL SUMMARY JUDGMENT

BASED ON FEDERAL PREEMPTION

Defendants argue that Plaintiff's claims are preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act"), 21 U.S.C. § 391 *et seq.*, which is enforced by the Food and Drug Administration ("FDA"), 21 U.S.C. § 393(b). Initially, Defendants primarily argued in support of their Motion that Plaintiff's failure to warn claim was preempted, anticipating that Plaintiff would seek to introduce evidence that Defendants' warnings about the risk of PPH from Redux should have been stronger, or should have contained a "black box" warning. In support of this argument, Defendants cited the FDA's new drug labeling rules, which were issued in January, 2006. The preamble to these rules states that the "FDA believes that under existing preemption principles, FDA approval of labeling under the act, whether it be in the old or new format, preempts conflicting or contrary State law." 71 Fed. Reg. 3922, 3934. The court notes that because Plaintiff has withdrawn her failure to warn claim, this argument is no longer pertinent. Thus, this portion of Defendants' Motion is denied as moot.

Defendants also argued that all of Plaintiff's claims are preempted because they conflict with the FDA regulatory process. As discussed below, the court finds that the FDCA preempts some, but not all, of Plaintiff's claims.

The purpose of the FDA is to

> (1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner;
> (2) with respect to such products, protect the public health by ensuring that--
> . . .
> (B) human . . . drugs are safe and effective; . . . .

21 U.S.C. § 393(b). In other words, the FDA is responsible for regulating which drugs are on the market and the warnings such drugs must provide. As such, Plaintiff's strict liability and negligence claims that Redux was an "unreasonably dangerous" drug for which no warning would have been adequate directly conflicts with the FDA's authority to determine which drugs are sufficiently safe and effective to be marketed. Although Plaintiff asserts that she alleges only that *Defendants* should not have marketed Redux, and that she does not argue that *the FDA* did anything wrong, the court finds that her claim that Redux should never have been placed on the market interferes with the FDA's objectives. Consequently, all claims relating to pre-FDA approval are preempted by the FDA. In addition, to the extent that Plaintiff alleges fraud-on-the-FDA or that Defendants concealed or misrepresented information to the FDA, these claims are preempted as well.

However, the FDCA does not preempt all product liability claims. Congress has expressly stated that the FDCA is not intended to preempt a state law unless it directly conflicts with the Act:

> Nothing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law.

Section 202 of the Drug Amendments of 1962 (Public Law 87-781, Title II, section 202, 76 Stat. 780, 793 (Oct. 10, 1962). Furthermore, in its most recent regulations, the FDA expressly stated that it "recognizes that FDA's regulation of drug labeling will not preempt all State law actions." 71 Fed. Reg. 3922, 3936.

The court notes that numerous product liability suits about defectively designed drugs are litigated and resolved pursuant to state law without any discussion of federal preemption. *E.g.*, *Saraney v. TAP Pharm. Prods.*, No. 1:04 CV 02026, 2007 U.S. Dist. LEXIS 3113 (N.D. Ohio

Jan. 16, 2007); *Yanovich v. Sulzer Orthopedics, Inc.*, No. 1:05 CV 2691, 2006 U.S. Dist. LEXIS 90332, at *33 (N.D. Ohio Dec. 14, 2006); *Kennedy v. Merck & Co., Inc.*, 2003 Ohio 3774 (Ohio App. Ct. 2003). In fact, the only court that appears to have addressed the issue of whether the FDCA preempts product liability claims brought under the Ohio Products Liability Act ("OPLA") summarily found that claims for defective design and negligence in keeping a product on the market were *not* preempted. In *In re Diet Drugs Prods. Liab. Litig.* ("*Mingus v. Wyeth*" or "*Mingus*"), No. 04-23744, 2006 WL 1071545, at *3 (E.D. Pa. Apr. 21, 2006), the court held that the plaintiff's claims that "Wyeth designed a defective product and was negligent in not taking Redux off the market sooner tha[n] it did . . . . [i]n essence, . . . that Wyeth failed in its post-approval duties" were not preempted. Furthermore, Defendants have cited nothing in the FDCA, FDA regulations, or case law that suggests that the FDA intended to preclude all design defect claims. Therefore, the court finds that Plaintiff's post-FDA approval design defect claims, under strict liability and negligence, are not preempted.

Finally, Plaintiff also contends that Defendants are collaterally estopped from arguing preemption because they previously litigated this issue in *Mingus*, No. 04-23744, 2006 WL 1071545, discussed above. In *Mingus*, a different plaintiff suffering from PPH, also allegedly caused by ingesting Redux, brought claims for negligence and strict liability against the same Defendants as in the instant case. *Id.* at *1. As here, the plaintiff in *Mingus* withdrew her failure to warn claim and pursued her other claims based on a design defect theory. *Id.* The court in *Mingus* addressed several of the issues present in the instant case, and ultimately denied the defendants' motion for summary judgment. *Id.* at 4. The parties to the instant case do not dispute that the *Mingus* action was not decided on the merits because the parties ultimately settled.

Plaintiff's argument that *Mingus* collaterally estops Defendants in this case is not well-taken. The Sixth Circuit has explicitly rejected the idea "that a district court's denial of summary judgment is entitled to preclusive effect . . . ." *Kovacevich v. Kent State Univ.*, 224 F.3d 806, 835 (6th Cir. 2000). In addition, the fact that the *Mingus* court declined to vacate its summary judgment order after the parties settled, as Plaintiff pointed out during oral argument, does not create any preclusive effect. Furthermore, there is also a good argument to be made that preclusion is not appropriate regarding federal preemption because the issue is primarily legal in nature. For these reasons, Defendants are not precluded from litigating any issue in the instant case. Accordingly, the court grants in part and denies in part Defendants' Motion for Partial Summary Judgment Based on Federal Preemption. (ECF No. 34.)

IV. MOTION FOR SUMMARY JUDGMENT BASED ON LACK OF EVIDENCE OF PROXIMATE CAUSATION

As discussed above, to the extent that Defendants' Motion seeks summary judgment on Plaintiff's failure to warn claim, the Motion is denied as moot. Furthermore, for the reasons discussed above, the court rejects Plaintiff's argument that Defendants are collaterally estopped from bringing this Motion.

A. Design Defect Claim

The OPLA governs product liability claims brought under Ohio law. Within the OPLA, O.R.C. § 2307.75 provides the standard for proving a design defect claim. The success of a potential design defect claim hinges, at least in part, on whether the warnings provided to physicians[3] about

[3] Plaintiff does not dispute that the "learned intermediary" doctrine applies, which states that the adequacy of a product's warning is determined by "whether *the doctor*, rather than the patient, would reasonably understand the risks." *Meridia Prods. Liab. Litig. v. Abbott Labs.*, 447 F.3d 861, 867 (6th Cir. 2006) (emphasis added); *see*

the product were adequate. Where the warning is found to be *inadequate*, a plaintiff is entitled to a rebuttable presumption that the inadequate warning proximately caused her to ingest the drug, which the defendants must then rebut. A plaintiff must also prove that ingestion of the drug proximately caused her injury. O.R.C. § 2307.73(A); *Seley v. G. D. Searle & Co.*, 67 Ohio St. 2d 192, 199-200 (Ohio 1981); *Kennedy*, 2003 Ohio 3774, at P17, P34, P36. On the other hand, Ohio statute provides that where a warning for an ethical drug is found to be *adequate*, then no design defect exists as a matter of law. The statute provides, in pertinent part:

> (D) An ethical drug or ethical medical device is not defective in design or formulation because some aspect of it is unavoidably unsafe, *if the manufacturer of the ethical drug or ethical medical device provides adequate warning and instruction* under section 2307.76 of the Revised Code concerning that unavoidably unsafe aspect.

O.R.C. § 2307.75(D) (emphasis added). In the instant case, Redux constitutes an "ethical drug," which is defined as "a prescription drug that is prescribed or dispensed by a physician or any other person who is legally authorized to prescribe or dispense a prescription drug." O.R.C. § 2307.71(4).

The parties disagree about the adequacy of the Redux warnings. Defendants argue that, by withdrawing her failure to warn claim, Plaintiff has conceded that Defendants' warnings were adequate. However, Plaintiff argues that it has not conceded that the warnings are adequate and that the adequacy of the warnings is a factual issue for the jury.

1. Burden of Proof Regarding Adequacy of Warnings

The parties disagree as to which party bears the burden of proof as to the adequacy of the warnings under Section 2307.75(D). Plaintiff argues that Defendants bear the burden of proving that

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O.R.C. § 2307.76(C). Consequently, the court's discussion of the disputed warnings refers to those warnings provided to physicians, not to Buchanan.

the warnings were adequate, while Defendants argue that Plaintiff bears the burden of proving that the warnings were inadequate. The statute itself does not state which party bears the burden.

In *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 815 (N.D. Ohio 2004), *aff'd*, *Meridia*, 447 F.3d 861, the court stated:

> *Generally, an adequate warning is a defense to design defect claims levied against prescription drugs. See, e.g.*, Ohio Rev. Code § 2307.75(D) ("An ethical drug . . . is not defective in design or formulation because some aspect of it is unavoidably unsafe, if the manufacturer of the ethical drug . . . provides an adequate warning and instruction . . . concerning that unavoidably unsafe aspect."); RESTATEMENT (SECOND) OF TORTS § 402A cmt. k ("There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs . . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous.").

(*emphasis added*). Another court in the Northern District of Ohio has quoted the statement from *In re Meridia* that "[g]enerally, an adequate warning is a defense to design defect claims," although the court did not expressly state that the defendant bore the burden of proof. *Yanovich*, No. 1:05 CV 2691, 2006 U.S. Dist. LEXIS 90332, at *33.

Plaintiff cites *Mingus*, No. 04-23744, 2006 U.S. Dist. LEXIS 17557, which relied on *In re Meridia* in concluding that Defendants bear the burden to prove that their warnings were adequate. The *Mingus* court held:

> The wording of § 2307.75(D) in our view makes the provision an affirmative defense. It does not require plaintiff to prove that the warning is inadequate. Rather, it provides a safe harbor for drug manufacturers if their warning is adequate. Unless the manufacturer proves that the warning is adequate, the safe harbor will not apply. In *In re Meridia Products Liability Litigation*, the District Court for the Northern District of Ohio read § 2307.75(D) in the same way we do. 328 F. Supp. 2d 791 (N.D. Ohio 2004). The court stated,

> "Generally, an adequate warning is a *defense* to design defect claims levied against prescription drugs." *Id.* at 815 (emphasis added).

Id. at *2.

The court finds that it is unclear whether the *In re Meridia* court intended its statement that "[g]enerally, an adequate warning is a defense to design defect claims levied against prescription drugs" to mean that "defense" was synonymous with "affirmative defense." Furthermore, none of the sources that *In re Meridia* cites state that the defendant bears the burden of proof regarding the adequacy of warnings. As previously stated, Section 2307.75(D) does not allocate the burden of proof. Neither does the Restatement (Second) of Torts § 402A (1965), which interprets section 2307.75(D), or its comments.

Although clearly not dispositive, it is worth noting that the Ohio Jury Instructions state that the plaintiff bears the burden of proof. The comments to the jury instructions state, in pertinent part:

> [O.]R.C. 2307.75(D)(E)(F).
>
> The statute does not specify whether the plaintiff or defendant carries the burden of proof or even the burden of producing evidence in subsections (D), (E) and (F) of R.C. 2307.75. Courts have placed the burden of proof on plaintiff. *Jacobs v. E. I. DuPont de Nemours & Co.* (6th Cir. 1995), 67 F. 3d 1219, 1242, *McGrath v. General Motors Corp.* (6th Cir. 2002), 26 Fed. Appx. 506, *Bloomer v. Van-Kow Enterprises* (May 5, 1994), 8th Dist. No. 64970.

Ohio Jury Instructions § 351.05 (italics omitted). The cases that the Ohio Jury Instructions cite all state that the plaintiff bears the burden for claims brought under Section 2307.75(F), which precludes liability for products where there is no "technically feasible alternative design." None of the cases cited discuss the burden of proof in Section 2307.75(D) claims. In *McGrath*, 26 F. App'x at 506, 510 (6th Cir. 2002), the Sixth Circuit held that the plaintiff bears the burden of production as to Section 2307.75(F), stating that "[t]he subsection does not state whether the plaintiff or defendant

bears the burden of production of an alternative design. Under Ohio case law, plaintiffs bear the burden of production." The *McGrath* court cited *Jacobs v. E. I. DuPont de Nemours & Co.*, 67 F.3d 1219, 1242 (6th Cir. 1995), for this proposition. The court in *Bloomer v. Van-Kow Enters.*, 1994 Ohio App. LEXIS 1937, at *7-*8 (Ohio Ct. App. 1994), also allocated the burden to the plaintiff to establish the feasibility of an alternative design. The fact that the Sixth Circuit has placed the burden on the plaintiff for subsection (F) weighs in favor of placing the burden on the plaintiff for subsection (D).

As such, a review of the statute and the case law suggests that the court in *Mingus* was not correct in concluding that the defendant bears the burden of proving the adequacy of warnings. While, admittedly, one reading of *In re Meridia* is that an adequate warning is an affirmative defense to a design defect claim, that court did not explicitly discuss which party bore the burden of proof. Furthermore, in cases involving Section 2307.75(F), which provides another exception to design defect liability without allocating the burden, courts have placed the burden of proof on the plaintiff. Therefore, for these reasons, the court finds that Plaintiff bears the burden of proving that Defendants did not provide adequate warnings.

2. Defendants' Warnings Are Adequate as a Matter of Law

Even assuming, *arguendo*, that Defendants bear the burden of proving that the Redux warnings were adequate, Defendants have presented sufficient evidence, which was uncontradicted by Plaintiff, to demonstrate that the warnings provided were adequate as a matter of law.

Courts use the following non-exclusive factors to determine whether a warning is adequate as a matter of law:

> 1. the warning must adequately indicate the scope of the danger; 2. the warning must reasonably communicate the extent or seriousness of the harm

> that could result from misuse of the drug; 3. the physical aspects of the warning must be adequate to alert a reasonably prudent person to the danger; 4. a simple directive warning may be inadequate when it fails to indicate the consequences that might result from failure to follow it and, … 5. the means to convey the warning must be adequate.

Saraney, No. 1:04 CV 02026, 2007 U.S. Dist. LEXIS 3113, at *16 (quoting *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 429 (Tenn. 1994)). In the instant case, the second factor is not relevant because Plaintiff does not allege misuse of the drug. Similarly, the fourth factor is not relevant because the warnings given were more detailed than a simple directive. Accordingly, the court will analyze whether the warnings satisfy the first, third, and fifth factors.

The first warning regarding the risk of PPH from Redux was provided in April, 1996, when the FDA approved the drug to be placed on the market. That warning, sent in a letter to health professionals, stated, in relevant part:

> ***Side Effects and Contraindications***
> . . . .
> There is also a small risk of a serious, potentially life-threatening cardiovascular condition, primary pulmonary hypertension (PPH) associated with the use of all types of prescription weight loss drugs. This risk is estimated to be about 18 cases per 1,000,000 users per year. In the general population, the yearly occurrence of PPH is 1 to 2 cases per 1,000,000 people.

(4/30/96 Letter, Defs.' Ex. E at 3, ECF No. 31-6.) On the first Redux label, the warning about PPH appeared at the beginning of the warnings section, it was written in all bold typeface, and it contained all of the above-quoted information. (4/29/96 Redux Label, Defs.' Ex. I at 1, ECF No. 31-10.)

Four months later, a second warning letter was sent out to health care professionals, entitled "Important Update in Redux (dexfenfluramine hydrochloride capsules) C-IV" in bold typeface. (8/22/96 Letter, Defs.' Ex. F, ECF No. 31-7.) This letter explained that a final report, which had reclassified data and included ten previously-excluded cases, indicated that the risk of PPH was more

prevalent than earlier stated. After repeating the statistics given in the previous warning, the letter stated:

> In the final report, the risk [of PPH] was calculated to be about 23 times higher for patients using anorexigens for 3 or more months compared to non-users. The incidence of PPH for patients taking anorexigens, including Redux, is now estimated to be between 23 and 46 cases per million patients per year.
>
> . . . .
>
> Although the incidence of PPH for patients taking anorexigens remains small, PPH is a serious disorder with an estimated 4-year mortality rate of 45%. Therefore, it is very important that Redux not be prescribed for cosmetic weight loss. Redux is indicated for use only in those patients who have a body mass index (BMI) of at least 30 kg/m (which is approximately 30 percent over desirable weight) or a BMI of at least 27 kg/m (which is approximately 20 percent over desirable weight) in the presence of other risk factors (e.g., hypertension, diabetes or hyperlipidemia).
>
> In order for the labeling of Redux to be consistent with the [final report on PPH] and to allow you to counsel your patients with accurate information, we are working with [the] FDA to revise product labeling appropriately. In the interim, this letter provides an overview of the . . . data to use as a reference in treating your obese patients.
>
> As indicated in the current labeling, patients should be advised to report immediately any deterioration in exercise tolerance. Treatment should be discontinued in patients who develop new, unexplained symptoms of dyspnea, angina pectoris, syncope, or lower extremity edema. These patients should be evaluated for the etiology of these symptoms and the possible presence of PPH.

(*Id.* at 1-2) (footnotes omitted).

The new labels were sent to health care professionals in December, 1996, along with a third letter explaining the changes made to the labels due to the findings described in the previous letter. (12/96 Letter, Defs.' Ex. G, ECF No. 31-8.) The December, 1996, letter stated, in pertinent part:

> **REDUX IS AN APPETITE SUPPRESSANT, AND APPETITE SUPPRESSANTS INCREASE THE RISK OF DEVELOPING PRIMARY PULMONARY HYPERTENSION, AN OFTEN FATAL DISORDER.**

> Use of appetite suppressants for longer than 3 months is associated with a 23-fold increase in the risk of developing PPH, a serious, potentially life-threatening cardiovascular condition. A 2-year case-control study identified 95 PPH cases; 30 of these had been exposed to appetite suppressants in the past, and 18 of the 30 had used appetite suppressants for longer than 3 months. Therefore, the risk associated with the long-term use of appetite suppressants was estimated to be about 23 to 46 cases per 1 million persons per year.

(*Id.* at 1.) A copy of the new label was included with this third letter. The new label provided the updated information on the study results and the increased risk of PPH in regular typeface. In addition, the above-quoted paragraph that appears in boldface and all capital letters also appeared in boldface and all capital letters on the new label. (10/23/96 Redux Label, Defs.' Ex. I at 3, ECF No. 31-10.)

As to the first factor, the court finds that the warnings clearly indicate the scope of the danger, namely, to what degree the use of diet aids such as Redux increase the risk of PPH, a fatal disease. As to the third factor, the court finds that the physical aspects of the warnings – use of capital letters and bold typeface and the placement in the warning section of the label – would alert a reasonably prudent physician to the danger. As to the fifth factor, the court finds that the labels and use of letters mailed directly to health care professionals about the change in labeling was an appropriate and sufficient means to convey the warnings.

The instant case is factually similar to *Yanovich*, No. 1:05 CV 2691, 2006 U.S. Dist. LEXIS 90332, at *33, *aff'd, Yanovich v. Zimmer Austin, Inc.*, No. 07-3058, 2007 U.S. App. LEXIS 27696, at *30 (6th Cir. Nov. 21, 2007), which granted summary judgment for the defendants on a design defect claim and, like here, did not involve a failure to warn claim. The *Yanovich* court found that the warnings were adequate as a matter of law where the defendants had presented evidence regarding the adequacy of the warnings and the "plaintiffs [had] *provide[d] no evidentiary support*

that the warnings were inadequate and [did] not designate expert medical testimony on the sufficiency of defendants' warnings." No. 1:05 CV 2691, 2006 U.S. Dist. LEXIS 90332, at *35-*36 (emphasis added).

In the instant case, Defendants have submitted evidence that Buchanan's physician, Dr. Evelyn Erokwu ("Dr. Erokwu"), recalls receiving letters from Wyeth about Redux, as well as evidence demonstrating that the three letters discussed above were in fact mailed to Dr. Erokwu at her office. (Dep. of Eveyln Erokwu ("Dr. Erokwu Dep.") 48-49, 52, 56, ECF No. 31-2.) At her deposition, Dr. Erokwu reviewed these letters and testified that while she did not have a specific memory of reading them previously, it was her standard practice to read letters containing prescription information about drugs that she prescribes. (*Id.* at 47-48, 53-55, 58.) The letters were dated between April and December, 1996, which means that the warnings were in effect during the time Buchanan allegedly took Redux.

Furthermore, it is undisputed that Plaintiff did not present any evidence to demonstrate that the warnings provided were inadequate, and instead argued solely that adequacy of the warnings was an issue of fact because Defendants bore the burden of proof. Consequently, as in *Yanovich*, Plaintiff has provided no evidence to controvert Defendants' evidence as to the adequacy of the warnings. Because the court finds that the warnings in the instant case were adequate as a matter of law, Plaintiff's design defect claim fails under Section 2307.75(D). Therefore, the court grants summary judgment for Defendants on Plaintiff's strict liability design defect claim.

B. Negligence Claim

1. Plaintiff's Allegations of Negligence

Plaintiff has not clearly stated the nature of her negligence claim. In her Amended Complaint, she states that Defendants had a duty

> to manufacture, promote, and sell only safe drugs, and the duty to investigate and disclose material facts about risks associated with their drugs. Defendants breached their duty by . . .[4] putting Redux on the market in 1996, when Defendants knew the active ingredient in th[is] drug[], namely, dexfenfluramine, was unreasonably dangerous. Defendants further breached their duty by . . . failing to update the drug['s] labels, failing to adequately monitor the effects of the drug[], failing to make timely . . . warning to the medical profession, failing to timely and accurately report to the FDA all adverse drug experience information obtained, and concealing and misrepresenting the results of studies to physicians and to the public.

(Am. Compl. ¶ 19.) Elsewhere in the Amended Complaint, Plaintiff further stated:

> 10. Dexfenfluramine, . . . in the form of . . . Redux, caused so many adverse health effects that it was and is unreasonably dangerous, no matter what warnings are given about the diseases it causes. At the time of its manufacture, the foreseeable risks associated with using dexfenfluramine exceeded the benefits associated with its use. Defendants had an obligation to know, analyze, and report relevant scientific and medical information relating to . . . and dexfenfluramine use. However, defendants failed to properly monitor for reports of adverse effects associated with such use. Further, defendants failed to perform adequate research and testing of the drug. Defendants concealed [and/or] misrepresented . . . [to] physicians and the public . . . the risks associated with such use.
>
> 11. Defendants widely promoted dexfenfluramine as safe, until September 15, 1997. On or about that date, Defendants withdrew . . . Redux from the market at the urging of the FDA, due to extremely high rates of serious adverse events. Defendants knew or should have known sooner that dexfenfluramine was a dangerously defective product, [and] they should never have marketed Redux . . . .

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[4] The court has deleted all references to Pondimin, another drug that Defendants manufactured that contained dexfenfluramine, because there are no allegations or evidence that Plaintiff ever ingested Pondimin.

(*Id.* ¶¶ 10-11.)

At oral argument, Plaintiff's counsel sought to distinguish her design defect claim from her negligence claim by stating that the design defect claim focused on whether the product was too dangerous to be used, whereas the negligence claim was "almost entirely focused on Wyeth's conduct." (1/17/08 Tr. at 26.) Plaintiff furthered characterized her negligence claim as alleging Defendants' failure to investigate the early warning signs that led to the drug being taken off the market and Defendants' failure to take the drug off the market sooner. (*Id.*)

The court finds that to the extent that Plaintiff's Complaint alleges claims for negligent misrepresentation or negligent failure to investigate or negligence in putting Redux on the market, these claims are preempted by the FDCA because, as previously discussed, they conflict with the FDA's regulatory authority. However, Plaintiff's allegations can also be read to comprise claims for general negligence and negligent design, which are not preempted by federal law.

2. Whether Plaintiff's Negligence Claim Survives the OPLA

Courts have held that some common law negligence claims, but not all, were abrogated by the enactment of the OPLA. In *Carrel v. Allied Prods. Corp.*, 677 N.E.2d 795, 798-99 (Ohio 1997), the Ohio Supreme Court held that negligent design claims were not precluded, reasoning that, "[a]ccording to principles of statutory construction, the General Assembly will not be presumed to have intended to abrogate a common-law rule unless the language used in the statute clearly shows that intent." As the language of the OPLA did not state that it was intended to "abolish common-law actions sounding in negligence," the court found that the negligent design claims survived. *Id.* at 789. In *Tompkin v. Am. Brands*, 219 F.3d 566, 575 (6th Cir. 2000), the Sixth Circuit held that the OPLA abrogated the plaintiff's negligence claim, but specifically distinguished *Carrel* on the ground

that the *Tompkin* plaintiff did not allege a negligent design claim. However, the Ohio Court of Appeals has held that a negligence claim was not preempted where the plaintiff's cause of action arose prior to the April 7, 2005, amendment of the OPLA, which provided that the OPLA is "intended to abrogate all common law product liability causes of action." *Luthman v. Minster Supply Co.*, 2008 Ohio 165, P13 (Ohio Ct. App. 2008). As in *Luthman*, the instant Plaintiff's cause of action arose prior to the amendment of the OPLA, and thus is arguably not precluded.

As previously indicated, the Sixth Circuit provides that Plaintiff's general negligence claim has been abrogated by the OPLA, and state law precedent provides that her negligent design claim has not been abrogated. However, even if the court were to find that Plaintiff's general negligence claim is not preempted, under *Luthman*, Plaintiff's negligence and negligent design claims fail on the merits because, as discussed below, she has not presented evidence that Defendants' actions or inactions proximately caused Buchanan's injury and death.

3. Merits of Plaintiff's Negligence Claim

Whether Plaintiff's negligence claim is characterized as a general negligence claim and/or a negligent design claim, Plaintiff has not met her burden to defeat summary judgment because she has not presented evidence showing that Defendants' negligence proximately caused Plaintiff's injury or death.

In Defendants' briefing, Defendants presented evidence in support of their Motion for Summary Judgment – in the form of Redux labels, FDA approval letters, and warning letters sent to physicians – that the warnings about the increased risk of PPH from Redux were adequate and that Defendants informed physicians and updated the warnings when new information became available. Defendants' evidence indicates that they provided the first Redux warning label in April, 1996, when

it was approved by the FDA; that they distributed a second letter in August, 1996, explaining that final results indicated that the risk of PPH was higher than previously stated; that they distributed the third letter along with the updated labels in December, 1996; and that Redux was ultimately taken off the market in September, 1997. Defendants also provided deposition testimony demonstrating that Buchanan's doctor, Dr. Erokwu, had received these warning letters. Furthermore, Defendants presented evidence that Dr. Erokwu recalled receiving information specifically about Redux's risk of PPH, and she testified that she was aware of the risk of PPH from diet drugs generally. (Dr. Erokwu Dep. at 57, 95-96.) Dr. Erokwu also recalled prescribing a diet pill for Buchanan, but did not recall which drug or for how long she prescribed it. (*Id.* at 93-94.) Dr. Erokwu also stated that it was her practice to discuss the risks of diet drugs with her patients before prescribing them. (*Id.* at 95-96.) Consequently, Defendants argue, Plaintiff cannot show that Buchanan's injury and death were proximately caused by anything that Defendants either did or did not do. Plaintiff did not present any evidence in response and instead argued that Defendants should have known that Redux was so dangerous that no warning would have been adequate and that the drug should have been taken off the market sooner.

Consequently, in the face of Defendants' evidence, Plaintiff has not put forward any evidence that Defendants did not take appropriate steps in providing adequate warnings about Redux, that Defendants should have taken Redux off the market sooner, or that Defendants' alleged failure to take Redux off the market sooner proximately caused Buchanan's injury and/or death. Under these circumstances, the court finds that Plaintiff has not met her burden of presenting evidence which creates a genuine issue of material fact. Therefore, the court grants summary judgment for Defendants on Plaintiff's negligence claim.

C. Wrongful Death Claim

Consequently, as the court has granted summary judgment for Defendants on Plaintiff's design defect and negligence claims, the court hereby grants summary judgment on Plaintiff's wrongful death claim pursuant to O.R.C. § 2125.01 *et seq.*

V. MOTION FOR PARTIAL SUMMARY JUDGMENT ON PUNITIVE DAMAGES

As the court has granted summary judgment to Defendants on all of Plaintiff's claims, Defendants' Motion for Partial Summary Judgment Relating to Punitive Damages (ECF No. 33) is hereby denied as moot.

VI. CONCLUSION

For the reasons stated above, to the extent that Defendants' Motions address Plaintiff's failure to warn claim, the Motions are denied as moot. Consequently, Plaintiff's failure to warn claim is hereby dismissed with prejudice. Furthermore, Defendants' Motion for Partial Summary Judgment Based on Federal Preemption (ECF No. 34) is granted in part and denied in part; Defendants' Motion for Summary Judgment Based on Lack of Evidence of Proximate Causation (ECF No. 31) is granted, and Defendants' Motion for Partial Summary Judgment Relating to Punitive Damages (ECF No. 33) is denied as moot. As a result of the above rulings, Plaintiff's case is hereby dismissed in its entirety.

IT IS SO ORDERED.

/s/ *SOLOMON OLIVER, JR.*
UNITED STATES DISTRICT JUDGE

February 28, 2008